

**REMARKS**

Reconsideration and allowance of the subject patent application are respectfully requested.

The office action indicates that Figures 1, 2A, 2B, 3A, 3B, 4, 5A, 5B, 6 and 8 should be labeled as --Prior Art--. In the Request for Approval of Drawing Changes filed concurrently herewith, Applicant proposes that Figure 1 be amended to reflect that the method provides for solving for a material properties matrix using optimization as discussed, for example, on pages 3 and 15-16 of the specification. Applicant further proposes that Figure 4 be amended to reflect that the finite elements may have a defined symmetry. Applicant also proposes that Figure 6 be amended to reflect that finite element module 802 provides for optimization and that the manufacturing instructions of Figure 8 are those from Figure 6. Accordingly, Applicant submits that Figures 1, 4, 6, and 8 need not be labeled prior art. Applicant respectfully submit that the changes to Figures 1, 4, 6, and 8 introduce no new matter. Figures 2A, 2B, 3A, 3B, 5A, and 5B have been labeled --Prior-Art-- as requested.

Claims 1, 4-9 and 22 were rejected under the judicially created doctrine of obviousness-type double patenting over certain allegedly corresponding claims of U.S. Patent No. 5,594,651. Claim 21 was rejected under the judicially created doctrine of obviousness-type double patenting over claim 15 of U.S. Patent No. 6,263,252. In both rejections, the office action states that the claims of this application are not patentably distinct from the claims of the prior patents because "the Applicant has not disclosed if and how specifying that the material properties of the finite elements have a particular symmetry affects the method of manufacturing." Reconsideration of the double patenting

rejection is respectfully requested. Independent claim 1 calls for a step of "specifying that the material properties of the finite elements have a particular symmetry" and for the material property matrix to be calculated based on the relationship  $\{f\} = [k] \{x\}$  *and the specified symmetry*. Thus, specifying that the material properties of the finite elements have a particular symmetry "affects" the method of manufacturing of claim 1 at least in terms of the material property matrix calculation. Because the stated basis for the obviousness-type double patenting rejection appears to be incorrect, reconsideration is respectfully requested.

Claims 1, 2, 4-10, 21-27 and 38-42 were rejected under 35 U.S.C. Section 103(a) as allegedly being unpatentable over St. Ville (U.S. Patent No. 5,796,617) in view of Wu *et al.* (U.S. Patent No. 5,654,077). The office action contends that although St. Ville does not teach a method that includes specifying a particular symmetry for the material properties of finite elements, Wu *et al.* remedies this deficiency. Applicant traverses this contention.

Wu *et al.* discloses stacking sequences that can be used to provide a multi-material fully isotropic laminate (MFIL) and a multi-material quasi-homogenous anisotropic laminate (MQHAL). A laminate is a flat plate or curved shell consisting of two or more plies stacked and bonded as an integral component for structural applications. Each ply is a uniform thickness layer of material. The arrangement of the material, thickness, orientation, and stacking sequence of the plies is referred to as the layup of the laminate. MFILs are obtained by shuffling the stacking sequences of certain laminates. As the number of plies increases, the possibility of finding a sequence that constitutes a MFIL also increases. Wu *et al.* refers to this problem of finding a sequence

as an "integer problem" and explains that a computer program is used to systematically search through integer distribution patterns to find patterns that that constitute a MFIL. MQHAL layups can be obtained by altering an MFIL.

It is respectfully submitted that the concept in Wu *et al.* of searching distribution patterns to find patterns that satisfy certain criteria would not have taught or suggested that the method of St. Ville be modified to specify a particular symmetry for the material properties of volume elements in a finite element model. As explained in the specification, imposing such symmetries on the solutions may improve manufacturability by defining a finite volume element ("voxel") in terms of properties that are the same, or that have certain symmetries, throughout that particular voxel. Wu *et al.* contains no such teaching nor can such a teaching or suggestion be fairly derived therefrom.

For at least these reasons, Applicant submits that claims 1, 2, 4-10, 21-27 and 38-42 are not rendered obvious by the proposed combination of St. Ville and Wu *et al.*

The proposed St. Ville-Wu *et al.* combination is likewise deficient with respect to those claims that depend from one of aforementioned claims. In addition, these dependent are believed to be allowable for additional reasons as stated above.

Claim 3 was rejected under 35 U.S.C. Section 103(a) as allegedly being unpatentable over the St. Ville-Wu *et al.* combination in further view of Legere *et al.* (U.S. Patent No. 6,087,571). Although the office action states that Legere *et al.* teaches that material properties of the finite elements are specified to be transversely isotropic, col. 6, lines 55-65 merely states that the described uniaxially oriented materials may be transversely isotropic. There is no mention of volume elements in a finite element model

nor of any symmetry thereof. Accordingly, Applicant submits that the proposed combination does not render claim 3 obvious.

Claims 11 and 28 were rejected under 35 U.S.C. Section 103(a) as allegedly being unpatentable over the St. Ville-Wu *et al.* combination in further view of Castanie *et al.* (U.S. Patent No. 6,290,889). It is alleged in the office action that Castanie *et al.* discloses composite materials comprised of structural fibers laminated in a matrix. Castanie *et al.* does not however remedy the deficiencies of the St. Ville-Wu *et al.* combination discussed above in connection with claims 1 and 25 (from which claims 11 and 28 depend). As such, even assuming that Castanie *et al.* were properly combinable with St. Ville and Wu *et al.*, the combination would not result in the subject matter of claims 11 and 28.

Claims 12 and 29 were rejected under 35 U.S.C. Section 103(a) as allegedly being unpatentable over the St. Ville-Wu *et al.*-Castanie *et al.* combination in further view of Rauscher *et al.* (U.S. Patent No. 4,889,526). Although the office action alleges that Rauscher *et al.* teaches a matrix of a composite material that includes biologic material, col. 37, lines 61-67 merely states that the human heart may be paced using, among other things, an *in vitro* or *in vivo* biologic material. There is no mention of incorporating such materials in a matrix into which structural fibers are laminated. Accordingly, Applicant submits that the proposed combination does not render obvious claims 12 and 29.

Claims 13 and 30 were rejected under 35 U.S.C. Section 103(a) as allegedly being unpatentable over the St. Ville-Wu *et al.*-Castanie *et al.* combination in further view of Johnson *et al.* (U.S. Patent No. 6,296,667). Although the office action alleges that Johnson *et al.* teaches a matrix that includes bone, Applicant understands Johnson *et al.*

to disclose a porous article used as a bone substitute material in which an osteoconductive or osteoinductive material such as bone may be provided in the interstices. There is no teaching or suggestion of incorporating bone in a matrix into which structural fibers are laminated. Accordingly, Applicant submits that the proposed combination does not render obvious claims 13 and 30.

Claims 14 and 31 were rejected under 35 U.S.C. Section 103(a) as allegedly being unpatentable over the St. Ville-Wu *et al.*-Castanie *et al.* combination in further view of Wack (U.S. Patent No. 6,126,659). Although the office action alleges that Wack teaches a matrix that includes crushed bone, col. 1, lines 21-22 and col. 1, lines 29-37 merely describe that crushed bone may be used in a femoral cavity. There is no teaching or suggestion of incorporating crushed bone in a matrix into which structural fibers are laminated. Accordingly, Applicant submits that the proposed combination does not render obvious claims 14 and 31.

Claims 15 and 32 were rejected under 35 U.S.C. Section 103(a) as allegedly being unpatentable over the St. Ville-Wu *et al.*-Castanie *et al.* combination in further view of Warren, Jr. (U.S. Patent No. 6,348,042). While the office action alleges that Warren, Jr. teaches a matrix that includes co-factors, the abstract merely states that enzymes impregnated into the interior of the lumen of a catheter require the presence of co-factors. Applicant does not understand the "matrix" mentioned in the abstract to be a matrix into which structural fibers are laminated. Accordingly, Applicant submits that the proposed combination does not render obvious claims 15 and 32.

Claims 16 and 33 were rejected under 35 U.S.C. Section 103(a) as allegedly being unpatentable over the St. Ville-Wu *et al.*-Castanie *et al.* combination in further view of

Tadros *et al.* (U.S. Patent No. 6,121,033). While the office action alleges that Tadros *et al.* teaches a matrix that includes biological cells, col. 14, lines 39-52 explain that the disclosed polymers do not have a toxic effect on microbes and that this same non-toxic behavior can be expected for other biological cells. Tadros *et al.* does not teach or suggest incorporating biological cells into anything, much less a matrix of a composite material as claimed. Accordingly, Applicant submits that the proposed combination does not render obvious claims 16 and 33.

Claims 17 and 34 were rejected under 35 U.S.C. Section 103(a) as allegedly being unpatentable over the St. Ville-Wu *et al.*-Castanie *et al.* combination in further view of Slaikou (U.S. Patent No. 6,231,590). While the office action alleges that Slaikou discloses a matrix that includes bio-active materials, col. 7, lines 15-21 merely state that bio-active materials may be used as a coating for a vaso-occlusion device. Slaikou does not teach or suggest incorporating bioactive materials in a matrix into which structural fibers are laminated. Accordingly, Applicant submits that the proposed combination does not render obvious claims 17 and 34.

Claims 18 and 35 were rejected under 35 U.S.C. Section 103(a) as allegedly being unpatentable over the St. Ville-Wu *et al.*-Castanie *et al.* combination in further view of Hermann (U.S. Patent No. 5,098,621). While the office action alleges that Hermann discloses a matrix that includes medications, col. 9, lines 49-55 merely state that a gauze "matrix" may be impregnated with medication. Hermann does not teach or suggest incorporating medications in a matrix into which structural fibers are laminated. Accordingly, Applicant submits that the proposed combination does not render obvious claims 18 and 35.

Claims 19 and 36 were rejected under 35 U.S.C. Section 103(a) as allegedly being unpatentable over the St. Ville-Wu *et al.*-Castanie *et al.* combination in further view of Phipps *et al.* (U.S. Patent No. 6,289,242). While the office action alleges that Phipps *et al.* discloses a matrix that includes antibiotics, col. 16, lines 46-50 merely state that antibiotics may be included in a gel matrix. Phipps *et al.* does not teach or suggest incorporating antibiotics in a matrix into which structural fibers are laminated. Accordingly, Applicant submits that the proposed combination does not render obvious claims 19 and 36.

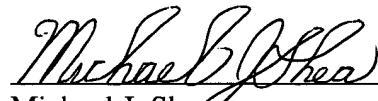
Claims 20 and 37 were rejected under 35 U.S.C. Section 103(a) as allegedly being unpatentable over the St. Ville-Wu *et al.*-Castanie *et al.* combination in further view of Mavity *et al.* (U.S. Patent No. 6,248,057). The office action alleges that Mavity *et al.* discloses a matrix that includes radioactive materials. Col. 2, line 1-5 state that a radioisotope may be bound to a biodegradable polymeric matrix. There is no disclosure that this matrix is one into which structural fibers are laminated. In any event, the proposed combination is deficient with respect to claims 1 and 25 from which claims 20 and 37 depend.

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At least for the foregoing reasons, it is believed that the application meets all formal requirements and that the pending claims properly distinguish the claimed subject matter over the prior art. Accordingly, favorable action is requested.

Respectfully submitted,

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